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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/022,138

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Thomas Schultz

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EXAMINER

QAZI, SABIHA NAIM

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/022,138	SCHULTZ ET AL.	
	Examiner	Art Unit	
	Sabiha Qazi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 9-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 9-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Non-Final Office Action

After an Appeal Conference, it was decided that this application would be reopened and new non-final rejections would be made.

Claims 1-17 are pending. Claims 1-8 are examined, 9-17 are withdrawn from consideration as non-elected invention. No claim is allowed.

Claim Rejections - 35 USC § 102—1st rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

1. Claims 1-8 are rejected under 35 U.S.C. 102(a) as being anticipated by GRAWE et al (US Patent 6,902,741 B1).

GRAWE et al discloses a transdermal system comprising a substrate and a sex hormone-containing adhesive matrix, wherein said sex hormone-containing adhesive matrix contains solid inclusions in dissolved form or dispersed form, said solid inclusions consist of a hydrophilic non-crosslinked polymer and a sex hormone, said solid inclusions have a concentration of said sex hormone of 20 to 90 percent by weight and said sex hormone is more than 95 percent by weight ***amorphous***.

The reference discloses, “predominantly amorphous inclusions of estrogenic and gestagenic steroids with up to 80% of active substance. Because the inhibiting function

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concerning the recrystallization of the active substance dissolved in the adhesive polymer is not required for this use, the amorphization capacity of the polymer can be fully exhausted.” (See lines 39-45 in col. 6)

The instant invention requires a hormonal product containing at least one steroid hormone in non-crystalline form. The reference discloses a sex hormone in an amorphous form, which anticipates the invention.

Claims 1-8 are rejected under 35 U.S.C. 102 (b) over GAST¹. GAST discloses a hormonal product with an excipient in crystalline and non-crystalline form, which is inherently taught by the reference applicant’s claimed invention. See the entire documents especially examples 1 and 2, claims, lines 10-19 and lines 31-67 in col. 7 of GAST.

Instant invention specifically claims the non-crystalline form while GAST is silent on specifically naming crystallized or non-crystallized formr of steroids (Even though GAST discloses “Preferred salts of estrone include but are not limited to the sodium and piperate salt,” it does not specifically use the words *crystalline* or *non-crystalline*, see lines 12-19, col. 7)).

See Exparte Novitski, 26 USPQ 2d 1389 (January 22, 1993) which is decision of USPTO Board of Appeals, holding to be inherent and not patentable, inoculating healthy plants with a known plant inoculant’s, employed in the prior art to protect them against phytopathogenic fungi. Novitski discovered that the known plant inoculants would also protect them against root dwelling plant pathogenic nematodes, a discovery neither known nor appreciated by the prior art.

¹ United States of America Patent No. 5,858,405.

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The step of inoculating plants with the same inoculants necessarily and inherently protects them against nematodes.

See Atlas Powder versus Ireco, 51 USPQ 2d 1943, (Fed. Cir. 1999), holds the failure of those skilled in the art to contemporaneously recognize an inherent property, function, or ingredient of a prior art reference does not preclude a finding of anticipation. Whether or not an element is inherent in the prior art is a fact question. Inherency is not necessarily conterminous with knowledge of those of ordinary skill in the art, who may not recognize the inherent characteristics or functioning of the prior art. However the discovery of a previously unappreciated property of a prior art composition does not render the old composition new to the discoverer.

The fact that prior art taught away from the claim is, in fact, only a showing that prior art did not recognize the inherent function. This lack of contemporary understanding did not defeat the showing of inherency.

As is clear from the above discussion and citations that GAST discloses crystalline and non-crystalline forms of steroid hormones such as estrones therefore non-crystalline form is inherently taught by the prior art of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject

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matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 are rejected under 35 U.S.C. 103(a) over GAST² and MERCK³. GAST teaches a hormonal product with an excipient in crystalline and non-crystalline form, which

² United States of America Patent No. 5,858,405.

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embraces applicant's claimed invention. See the entire documents especially examples 1 and 2, claims, lines 11-19 and lines 31-67 in col. 7 of GAST.

Instant claims differ from GAST in claiming a broader scope of non-crystalline steroid hormone. The only difference between the instant invention and GAST is that the instant invention specifically claims the non-crystalline form while GAST is silent on specifically naming crystallization (Even though GAST discloses "Preferred salts of estrone include but are not limited to the sodium and piperate salt," it does not specifically use the words *crystalline* or *non-crystalline*). This is where MERCK is used. MERCK, in cited section 3751, teaches that estrone *can be* crystallized which means that it was not crystalline before. Also it can be used as estrones or its salts which can be crystallized or non-crystallized.

It would have been obvious to one skilled in the art to prepare additional beneficial compositions for hormone replace therapy and other estrogen deficiencies because GAST teaches all limitations of the instantly claimed invention. Since GAST is silent on crystallization, the Examiner has cited MERCK, which teaches the crystallization process of estrone to show that estrone exists in both non-crystalline and crystalline forms.

Since no unexpected results and/or criticality seen, it would have been *prima facie* obvious to make and/or use non-crystalline form from the teaching of GAST.

The instant invention is *prima facie* obvious over the combined teachings of the prior art of record. A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re opprecht* 12 USPQ

³ Merck Index, 12th edition, page 632 (3751)

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2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).


Accordingly, the burden of proof is upon applicants to show that instantly claimed subject matter is different and unobvious over those taught by prior art. See *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is 571-272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


SABIHA QAZI, PH.D
PRIMARY EXAMINER

Thursday
April 27 2006